

COMMISSIONING POLICY FOR FUNCTIONAL ELECTRICAL STIMULATION FOR FOOT DROP OF NEUROLOGICAL ORIGIN

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Document Status

This is a controlled document. Whilst it may be printed, the electronic version posted on the CCGs' websites is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this policy should not be saved onto local network drives but should always be accessed from the Intranet / Internet.

NHS FUNDING

CCGs buy healthcare on behalf of their local populations. They each have a fixed budget for this and are required by law to keep within this budget. Demand for healthcare is greater than can be funded from this fixed budget. Unfortunately, this means that some healthcare which patients might wish to receive and which professionals might wish to offer cannot be funded.

CCGs prioritise what they spend, so that their local populations get access to the healthcare that is most needed. This assessment of need is made across the whole population and wherever possible, on the basis of best evidence about what works. They aim to prioritise in a way that is fair, so that different people with equal need have equal opportunity to access services.

ASSISTANCE WITH THE APPLICATION OF THIS POLICY AND UPDATES

This policy has been prepared to reflect the situation at the time of its development, and will require periodic review to reflect subsequent changes in law, guidelines, evidence etc.

For advice and assistance in relation to the application of this policy, and to obtain updates, please contact your local Clinical Commissioning Group (CCG).

This policy has been prepared by East Midlands Affiliated Commissioning Committee (EMACC). EMACC has been established as a joint committee of nineteen participating CCGs in the East Midlands to enable CCGs to work collaboratively on the development and maintenance of Commissioning Policies.

1. NHS Southern Derbyshire CCG
2. NHS North Derbyshire CCG
3. NHS Erewash CCG
4. NHS Hardwick CCG
5. NHS Nottingham City CCG
6. NHS Nottingham West CCG
7. NHS Nottingham North & East CCG
8. NHS Rushcliffe CCG
9. NHS Newark & Sherwood CCG
10. NHS Mansfield & Ashfield CCG
11. NHS Corby CCG
12. NHS Nene CCG
13. NHS West Leicestershire CCG
14. NHS Leicester City CCG
15. NHS East Leicestershire & Rutland CCG
16. NHS Lincolnshire West CCG
17. NHS South West Lincolnshire CCG
18. NHS South Lincolnshire CCG
19. NHS Lincolnshire East CCG

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1. EQUALITY STATEMENT

EMACC and its participating CCGs aim to create policy documents that meet the diverse needs of the populations to be served and the NHS workforce has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.

CCGs are committed to ensuring equity of access and non-discrimination, irrespective of age, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

This policy takes into account current UK legislative requirements, including the Equality Act 2010 and the Human Rights Act 1998, and promotes equality of opportunity for all. This document has been designed to ensure that no-one receives less favourable treatment owing to their personal circumstances.

2. DUE REGARD

In carrying out their functions, CCGs must have due regard to the Public Sector Equality Duty (PSED). This applies to all the activities for which CCGs are responsible for, including policy development and review.

3. POLICY STATEMENT

EMACC's participating CCGs will commission the wired version of Functional Electrical Stimulation (FES) using skin surface electrodes for patients with foot drop of neurological origin. Based on the evidence of clinical and cost effectiveness provided in this document, FES will be commissioned for patients (adults and children) meeting the following criteria:

- The patient has foot drop caused by upper level nerve damage
- The patient has been assessed by a specialist in foot drop of neurological origin and all treatment options have been considered
- There is evidence that foot drop has caused trips or falls, or gait issues causing significant clinical problems
- The patient can walk a minimum of 10 metres independently (+/- aids)
- The patient can physically manage a FES (+/- minimal assistance)
- The patient's cognitive ability is such that they can manage a FES independently
- The patient does not have co-morbidities which would affect their capacity to benefit from FES
- The patient does not have any of the accepted clinical contraindications to FES
- Clear FES treatment goals and expectations of benefit are outlined

Other types of FES (implanted or wireless) are not commissioned. This policy only covers lower limb FES for foot drop.

It is recommended that this policy should be reviewed periodically in the light of further research, follow up data on outcomes (including quality of life measures), duration of FES use and the maintenance of provider costs within an acceptable cost-effectiveness threshold.

Providers of FES services have previously sought prior approval from East Midlands CCGs for new patients that they consider suitable. A prior approval form is available to accompany this policy.

For patients already being treated who require funding for maintenance and support, the following criteria apply:

The patient will have objectively demonstrated (using validated tools) that the use of FES is still clinically appropriate, including:

- Evidence of foot drop which impedes gait that meets the criteria in this policy
- Documented improvement in clinical parameters from its use

4. PURPOSE OF THE POLICY

4.1 Aims and Objectives

This policy sets out the commissioning criteria for the NHS provision of the wired version of Functional Electrical Stimulation (FES), for people with upper motor neurone deficits causing drop foot and impacting on gait, risk of falls and walking ability. It is based on an assessment of the evidence of clinical and cost effectiveness and affordability. The policy assesses evidence for FES used as an orthotic device and assesses external skin surface electrodes only. The policy does not address the therapeutic use of FES as part of a battery of treatments, often used in physiotherapy departments.

The original evidence review for this policy updates that undertaken for NICE IPG278. The subsequent policy update includes evidence up to 2016.

4.2 Scope of the Policy

This policy area falls under the commissioning responsibility of CCGs. The policy is applicable to patients (adults and children) registered with General Practitioners (GPs) which are members of the CCGs which constitute EMACC.

5. THE MEDICAL CONDITION

Upper motor neurone lesions caused by multiple sclerosis, stroke, cerebral palsy or spinal cord injury have a range of physical consequences. These include muscle weakness, joint instability, arm flexion and leg extension hypertonicity, or hypotonicity, exaggerated reflexes and an extensor plantar response. Physically these may translate into a range of

symptoms including bladder dysfunction, pain, fatigue and problems with gait such as foot drop.

Foot drop is one of the most common manifestations of upper motor neurone lesions and results from weakness or lack of voluntary control in the ankle and foot dorsiflexors, causing the toes to drag and the foot to then drop during the normal gait pattern. This is likely to increase the risk of falls as well as the effort required to walk. Other approaches to treating foot drop include physiotherapy and ankle-foot orthoses (AFO) and the evidence of the clinical and cost effectiveness of Functional Electrical Stimulation (FES) as an alternative, has been considered here.

6. THE PROCEDURE / TREATMENT

Functional Electrical Stimulation (FES) has been designed to help people with neurological lesions, including drop foot, to move more easily. It works by producing muscle contractions that mimic normal voluntary gait movement by applying electrical pulses to nerves either directly (if implanted) or across the skin (if externally placed). It has been tested as a therapeutic intervention/treatment whereby the benefits persist once the FES has ceased or as an orthotic device whereby the benefits occur whilst the device is used. Whether FES is used as a therapeutic or orthotic device is at the moment largely a local clinical decision and depends upon the neurological condition. It is the orthotic properties of the device in the management of foot drop that are the focus of this policy. Implanted FES electrodes are usually inserted into the epineurium of the peroneal nerve under general anaesthesia. Electrodes may be percutaneous (passed through the skin and connected to an external pulse generator) or fully implanted and operated by radiofrequency waves. Alternatively, skin surface electrodes may be placed over the nerve and connected by leads to a stimulator unit, controlled by a foot switch. It is the external skin-surface FES that is the focus of this policy.

7. EXISTING CLINICAL GUIDANCE DOCUMENTS

The evidence for efficacy and safety of FES have been reviewed by NICE in IPG278 (2009) which states that the efficacy (improving gait) and safety of Functional Electrical Stimulation (FES) for foot drop of central neurological origin appears adequate to support its use under normal clinical governance and audit arrangements. This 2009 guidance is also referenced in the 2013 NICE guideline for stroke rehab in adults and the 2014 guideline for Multiple Sclerosis in adults. An important evidence update by Healthcare improvement Scotland and endorsed by the Scottish Health Technologies group (2012) found that,

“...functional electrical stimulation (FES) (mainly using surface electrodes) is associated with improved walking speed and reduced walking effort.”

This evidence update notes that there are few safety concerns around the use of surface-applied FES, and the conservative base case cost per QALY of approximately £19,239 compared to standard physiotherapy.

The Scottish Intercollegiate Guidelines Network (SIGN 2010) has published guidelines on the management of patients with stroke. Regarding FES they conclude that:

“Electrostimulation may be an effective intervention for some patients, with specific problems, when delivered in a specific way, although there is presently insufficient evidence to determine which selected patients may benefit.”

“Functional Electrical Stimulation may be considered as a treatment for drop-foot, where the aim of treatment is the immediate improvement of walking speed and/or efficiency. (Evidence grade C)”

The Royal College of Physicians National Clinical Guidelines for Stroke (2008) recommends:

- Functional electrical stimulation of the arm or leg should not be used on a routine basis outside the context of clinical trials.
- Functional electrical stimulation of the leg should only be considered and used for individual patients who:
 - have footdrop impeding gait not satisfactorily controlled using ankle–foot orthoses *and*
 - have demonstrable gait improvement from its use

The Royal College of Physicians National Guidelines for MS (RCP, 2004), also emphasise the need to implement a proactive and preventative approach at an early stage.

Both the NICE guidelines for MS (NICE 2003) and National Service Framework for Long Term Conditions (Department of Health 2007) encourage the utilisation of any modalities that improve patient mobility and social access and suggest that technology should be embraced in the clinical setting.

8. EPIDEMIOLOGY

Estimates of the prevalence and incidence of foot drop in the UK caused by neurological deficits are difficult to find due to the range of neurological disorders causing upper neurone lesions and variability in the symptoms, often not reported.

The Multiple Sclerosis Society (2009) reports an estimate of 100,000 for the number of people in the UK with MS.

A study of the UKGP database estimated that 126,669 people were living with MS in the UK in 2010 (203.4 per 100,000 population) and that 6,003 new cases were diagnosed that year (9.64 per 100 000/year). There is an increasing population living longer with MS, which has important implications for resource allocation for MS in the UK.

The Stroke Association estimates that over 300,000 people are living with moderate to severe disabilities as a result of stroke. If only 1% of these people seek FES as a treatment option there are potentially 4000 people in the UK at any one time that may do so.

The population of the East Midlands represents approximately 7.1% of the total UK population (ONS figures below) so the demand for FES in the East Midlands could be from 284 patients at any one time.

UK Pop 65.1 million,
EM Pop 4.6 million.
EM = 7.1% of UK population

Data collected from East Midlands CCGs showed that 65 new requests were received from services in 2014/15.

9. CLINICAL EFFECTIVENESS EVIDENCE SUMMARY

The methodology for review and more detailed evidence appraisal can be found in the accompanying evidence document. Current evidence on the safety and efficacy (in terms of improving gait) of Functional Electrical Stimulation (FES) for drop foot of central neurological origin appears adequate to support the use of this device provided that normal arrangements are in place for clinical governance, consent and audit. There are a number of trials and several recent systematic reviews into the effectiveness of FES in limb dysfunction. However, most of the available evidence comes from small studies with short intervention period.

The initial publication of this policy found that overall the literature reviewed was heterogeneous in nature making robust conclusions difficult to make. A significant number of studies did however suggest that FES can have a beneficial orthotic effect for some patients in terms of walking speed and reduced effort. However, a systematic and direct comparison of the benefits of FES compared with Ankle Foot Orthosis (AFO) was not possible as many studies used exercise or physiotherapy as the comparator group, rather than AFO and we did not review the evidence of effectiveness of AFO. Studies that did compare FES and AFO were generally of poor quality. They did not suggest superiority of either FES or AFO clinically but generally patients showed a preference for FES. There were too few published studies on the effect on falls and quality of life to draw firm conclusions regarding the benefits of FES.

(For a detailed review of evidence from previous guideline please see appendix 2)

10. SAFETY

There does not appear to be any significant safety issues related to the use of the skin applied FES, and it appears to be well tolerated and preferred.

11. COST EFFECTIVENESS EVIDENCE SUMMARY

One economic evaluation (Centre for Evidence-based Purchasing, 2010) modelled the cost effectiveness of FES in stroke patients using efficacy data with physiotherapy as a comparator. The use of AFO and FES in other populations was not therefore included in the model.

The base case analysis, updated to 2009 figures, suggested an average ICER over a 5 year time horizon of £19,239. For year one the ICER was £52,337 and £10,964 for each subsequent year. The high up-front costs of equipment and consultations accounted for the skew towards earlier higher costs.

The report concluded that, at a threshold willingness to pay of £30k, there is a probability of 66% that FES is cost-effective. From the same data, at a lower threshold willingness to pay of £20k, the probability that FES is cost effective falls to 20%. See Fig 1.

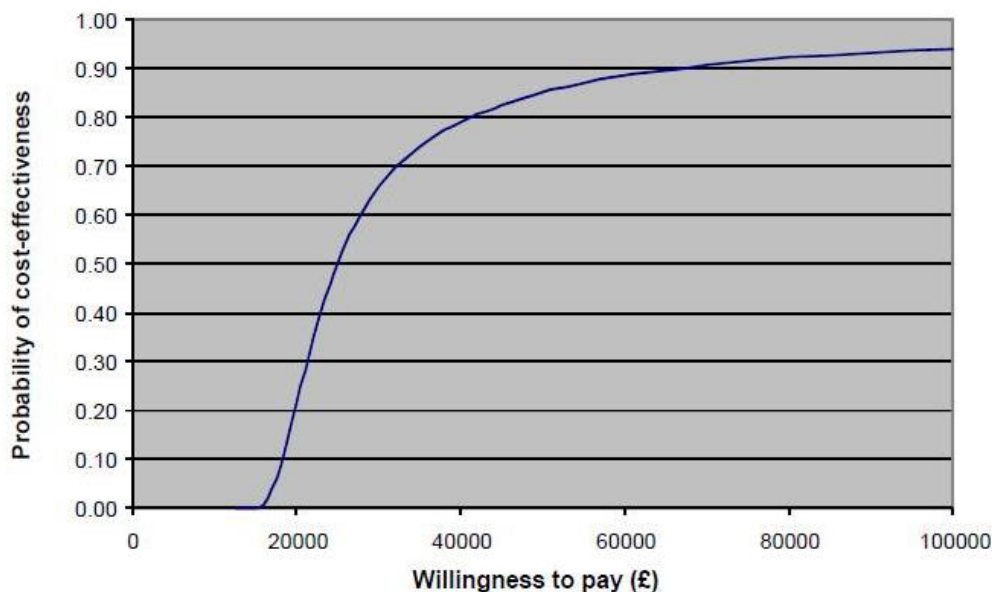


Fig 1. Overall (5 year) cost-effectiveness acceptability. CEP, 2010. p19.

The model is sensitive to gains in health utility (acknowledged as a weak area in the literature) and patient selection, requiring long term commitment to achieve cost effectiveness within accepted parameters for the NHS.

Given the lack of cost effectiveness data, further information was requested from the UK Salisbury team directly. Data from this group suggested a mean QALY gain of 0.065 from using FES and a mean length of FES use of 4.4-4.9 years based on clinical audit. Using 2007 costs the author suggested a cost per quality adjusted life year of £25,231 in the first year and £12,431 if used over 5 years. However, there was no mention of discounting or sensitivity analysis.

The only study of note was Taylor et al. (2013). It reported a mean QALY gain of 0.041 and a cost per QALY of £15,406 for all users over 4.9 years. Sub-group analysis was also done for people with stroke and a cost per QALY of £15,268 over 5 years was reported. In this circumstance an ICER for FES compared with physiotherapy or any other comparator was not presented.

No further UK specific cost-effectiveness data has been published between the above discussed studies; in particular further cost-effectiveness data regarding the wireless apparatus is needed.

Costs of FES Equipment (2017)

Current reference costs of equipment are **£804** (inc. VAT) per unit of the Odstock PACE device. Additional costs include electrodes (requiring on average 1 pack per month, at £12.30 per pack) and replacement leads and footswitches as required.

Summary of cost-effectiveness evidence

A critical analysis of the cost effectiveness data available identified a number of issues:

- Equivocal evidence about a significant effect of FES on quality of life
- Lack of robust evidence as to the persistence of FES effects over time and duration of patient use of FES
- Variability in costs from local providers

12. COMMISSIONING POLICY

Based on the evidence of clinical and cost effectiveness provided in this document, the wired version of FES using skin surface electrodes, for foot drop, will be commissioned for patients (adults and children) meeting the following criteria:

- The patient has foot drop caused by upper level nerve damage
- The patient has been assessed by a specialist in foot drop of neurological origin and all treatment options have been considered
- There is evidence that foot drop has caused trips or falls, or gait issues causing significant clinical problems
- The patient can walk a minimum of 10 metres independently (+/- aids)
- The patient can physically manage a FES (+/- minimal assistance)
- The patient's cognitive ability is such that they can manage a FES independently
- The patient does not have co-morbidities which would affect their capacity to benefit from FES
- The patient does not have any of the accepted clinical contraindications to FES
- Clear FES treatment goals and expectations of benefit are outlined

Other types of FES (implanted or wireless) are not commissioned. This policy is only applicable to lower limb devices.

It is recommended that this policy should be reviewed periodically in the light of further research, follow up data on outcomes (including quality of life measures), duration of FES use and the maintenance of provider costs within an acceptable cost-effectiveness threshold.

13. EXCEPTIONAL CIRCUMSTANCES

CCGs will consider individual cases for funding outside this commissioning policy in accordance with their Individual Funding Request (IFR) Policy which sets out a decision making framework for determining these cases. For an IFR request to be considered, it must be demonstrated that the patient fulfils the strict criteria for exceptionality.

It should be noted that the criteria for exceptionality is very unlikely to be satisfied if an individual is part of an identifiable cohort of patients, who at the same disease stage would derive similar benefit from the intervention.

14. PATIENT PATHWAY

Providers of FES services have previously sought prior approval from East Midlands CCGs for new patients that they consider suitable. A prior approval form is available to accompany this policy.

For patients already being treated, who require funding for maintenance and support, the following criteria apply:

The patient will have objectively demonstrated (using validated tools) that the use of FES is still clinically appropriate, including:

- Evidence of foot drop which impedes gait that meets the criteria in this policy
- Documented improvement in clinical parameters from its use

APPENDICES

Appendix 1: Summary Evidence Table

Quality (Level of evidence)	Study Design	Presents positive results for FES	Quality score using SIGN scoring	Study Design	Presents equivocal or negative results for FES	Quality score using SIGN scoring
Level 1	Systematic Review	Howlett et al, 2015	1+	Systematic review	Mehrholz et al., 2008	1+
	RCT	Bethoux et al. 2015	1+	Economic report	CEP 2010	1+
	RCT	O'Dell et al. 2014	1+	RCT	Barrett et al., 2009	1+
	Randomised crossover trial	Embrey et al. 2010	1+	Systematic review	Pomeroy et al., 2009	1+
	RCT	Ng et al. 2008	1+	RCT	Kottink et al., 2008	1+
	Meta-analysis	Kottink et al. 2004	1+	Controlled trial	Sabut et al., 2010	1+
	RCT	Pool et al. 2015	1-	RCT	Sheffler et al 2013	1-
	RCT	Wilkinson et al 2014	1-	RCT	Mesci et al. 2009	1-
	RCT	Chung et al 2014	1-	Systematic review	Hamzaid and Davis 2009	1-
	Randomised crossover trial	Taylor et al. 2014	1-	RCT	Van der Linden 2008	1-
	Randomised crossover trial	Everaert et al 2013	1-	RCT	Tanovic et al 2009	1-
	RCT	Esnouf et al. 2010	1-			
	Systematic review	Roche et al. 2009	1-			
	RCT	Kojovic et al. 2009	1-			
	RCT	Burridge et al., 1997	1-			
Level 2	Controlled trial	Shendkar et al. 2015	2++	Systematic review	Seifart et al., 2009	2++
	Controlled trial	Nolan et al. 2015	2+			
	Controlled trial	You et al. 2014	2+			
	Uncontrolled trial	Damiano et al. 2013	2+			
	Uncontrolled trial	Melihan et al. 2013	2+			
	Uncontrolled trial	Springer et al. 2013	2+			
	Uncontrolled trial	Scott et al. 2013	2+			
	Matched cohort	Marsden et al. 2013	2+			
	Crossover trial	Van Swigchem et al., 2010	2+			
	Uncontrolled trial	Seifart et al., 2010	2+			
	Uncontrolled trial	Barrett et al. 2010	2+			

	Uncontrolled trial	Stein et al. 2009	2+			
	Case-control	Paul et al. 2008	2+			
	Uncontrolled trial	Taylor et al., 1999	2+			

For Level 3 evidence considered in this review please see references list and also accompanying evidence document

Appendix 2: Detailed discussion of evidence from evidence review

Clinical effectiveness evidence

In total, 30 published articles were reviewed relating to the orthotic effect of FES including 6 systematic reviews (1 meta-analysis), 12 controlled (\pm randomised) trials, 9 uncontrolled or before and after trials, 1 observational study, 1 economic review, and 1 case series. The studies were heterogeneous in their patient groups, use of FES technology, comparators and outcome measures, as well as in their conclusions. Tables 1 and 2 summarise the quality and design of the studies reviewed and Table 3 shows studies that were excluded from the clinical effectiveness analysis.

Studies that demonstrate an orthotic effect of FES

Studies have used various protocols, devices and lengths of use of FES with a range of outcomes, both positive and negative. There were 15 studies that reported a positive orthotic effect of FES on the treatment of drop foot, including two systematic reviews.

In one review, Roche et al. looked at a range of different study methodologies including before and after studies, FES versus an alternative therapy and FES combined with another therapy but were unable to pool any outcome measures in a meta-analysis due to the heterogeneity of study designs. Most studies were at moderate or high risk of bias and no 'grey literature' was included in the search protocols. The authors concluded that there is an orthotic effect of FES, particularly when combined with other therapies (e.g. botulinum toxin injections or electromechanical gait training) and this includes faster walking speed (ranges from 7% to 19% in before and after studies) and lower effort (ranges from 19% to 37% in two before and after studies). However the review does not explicitly state how the outcomes measured might impact quality of life or what the clinical significance of the observed increases in walking speed and decreases in physiological cost might be.

In a second systematic review Kottink (2004) did calculate pooled estimates on walking speed and found that FES increased walking speed by 0.13 m/s or 38% however they were not able to generate pooled estimates of changes in effort due to the small number of included studies.

Barrett et al. (2010) reported improved quality of life measures following FES use in MS patients but there were significant selection and measurement biases in this study. For example, there was no discussion of the eligibility of patients for FES, criteria for inclusion in the study or whether data was collected from patients that withdrew from FES use. In addition, there was no control group so it is not clear if the improved quality of life was due to FES alone or the fact that patients had additional clinical input.

Esnouf et al. (2010) reported improved satisfaction and performance with activities of daily living in patients referred for FES who met the studies inclusion criteria. In addition, this study was the only one to consider falls as an outcome measure. The FES group had fewer falls in total compared to the group assigned to exercise (5 compared to 18 in the exercise group).

Of the non-review studies, all except Esnouf (and possibly Mesci) included at least one walking speed measure but each study used a different testing paradigm for the FES intervention. For example, Ng et al looked at outcomes after 4 weeks of FES use, Embrey et al used 3 months of FES use plus a walking regime, Stein et al used FES for 3 months alone and Kojovic et al used 4 weeks plus a walking therapy. However, these studies did report an orthotic effect of FES on walking speed. Several studies reported a reduction in physiological cost index (an indication of effort of walking). Many of the studies showing a positive effect of FES were uncontrolled trials or before and after studies where the results of walking speed were presented after a period of FES use, but with no comparator group that had an alternative intervention. Overall these data suggest

that FES can increase walking speed but from the literature we have reviewed it is not possible to say if this is significantly advantageous over other orthoses.

Studies that demonstrate equivocal or negative results for the orthotic effect of FES

Three high quality and one lower quality systematic reviews (Mehrholz, 2008; Pomeroy, 2009; Hamzaid and Davis, 2009; Seifar, 2009) report that there is inconclusive evidence about the effectiveness of FES in the treatment for drop foot. A common theme is that the literature is too heterogeneous in terms of the intervention protocols used and outcomes measured to be able to provide pooled effect measures.

Barrett et al showed in an RCT that the FES intervention groups had a slower walking speed, no difference in effort and no difference in distance covered compared to an exercise group at 18 weeks having adjusted for differences in baseline measures. In a study of children with cerebral palsy, (Van der Linden, 2008) showed slower walking speed but a significant improvement in gait kinematics with FES switched on (orthotic effect).

Studies that directly compare FES and AFO

Only 4 studies were found that compared FES directly with AFO. These were all of moderate to low quality. Ring et al., studied different gait parameters within the same patients using FES and when using an AFO. They found no difference in walking speed between the two orthoses at 4 and 8 weeks and no difference in gait stability and symmetry at 4 weeks but these improved in the FES group at 8 weeks.

Sheffler et al., 2006 again used a within-patient trial design comparing outcomes of FES, AFO and no device in terms of ambulation and patient preference. Both FES and AFO improved ambulation profiles compared to no orthotic but there was no difference between FES and AFO. Patients did however prefer FES.

Again van Swigchem et al., 2010 showed that compared to AFO FES did not result in an increase in walking speed or activity level but again patients preferred it and the same authors reported a single case study of a man for whom surface FES was not suitable but showed near normal gait after having FES implanted.

GLOSSARY

Word/Abbreviation	Meaning
Ankle foot orthosis	A brace used to stretch the Achilles tendon worn on the lower leg and foot to support the ankle, hold the foot and ankle in the correct position and correct foot drop. It is a thin, light plastic material (www.scope.org.uk).
Cerebral Palsy	The term used to describe a group of conditions characterised by varying degrees of paralysis and originating in infancy or early childhood. In some 80 per cent of cases this takes the form of spastic paralysis (muscle stiffness). (Blacks Medical Dictionary, 42 nd Ed).
Commissioning	Commissioning in the NHS is the process of ensuring that the health and care services provided effectively meet the needs of the population. It is a complex process with responsibilities ranging from assessing population needs, prioritising health outcomes, procuring products and services, and managing service providers. (Taken from www.dh.gov.uk).
East Midlands Specialised Commissioning Group (EMSCG).	Specialised Commissioning is the means by which Primary Care Trusts (PCTs) work together to plan, buy and manage services which treat patients with rare conditions. (Taken from www.emscg.nhs.uk) For the East Midlands this is the East Midlands Specialised Commissioning Group.
Economic evaluation	An economic evaluation is used to assess the cost effectiveness of healthcare <i>interventions</i> (that is, to compare the costs and benefits of a healthcare intervention to assess whether it is worth doing). The aim of an economic evaluation is to maximise the level of benefits - health effects - relative to the resources available. (www.nice.org.uk).
Extensor plantar response	An abnormal reflex of the big toe (http://www.online-medical-dictionary.org/).
Gait	The way in which an individual walks. (Blacks Medical Dictionary, 42 nd Edition).
Health utility	In the analysis of health outcomes, utility is a number between 0 and 1 that is assigned to a state of health or an outcome. Perfect health has a value of 1. Death has a value of 0. (www.medicinenet.com).
Heterogenous	The term is used in <i>meta-analyses</i> and <i>systematic reviews</i> to describe when the results of a test or treatment (or estimates of its effect) differ significantly in different studies. Such differences may occur as a result of differences in the <i>populations</i> studied, the outcome measures used or because of different definitions of the <i>variables</i> involved. It is the opposite of <i>homogeneity</i> . (www.nice.org.uk).
Hypertonicity	Increased tension in the muscles.
Meta analysis	A method often used in <i>systematic reviews</i> . Results from several studies of the same test or treatment are combined to estimate the overall effect of the treatment. (www.nice.org.uk).
Multiple Sclerosis (MS).	Multiple Sclerosis (MS) is a condition of the central nervous system (www.mssociety.org.uk).
National Institute for Health and Care Excellence (NICE).	NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. (NICE, 2009).
Orthotic device	A support, brace, or splint used to support, align, prevent, or correct the function of movable parts of the body (www.medicinenet.com).
Physiological	Science of the normal function of living things. (Collins English Dictionary, 1994).
Physiotherapy	Treatment of disease or injury by physical means such as massage, rather than by drugs. (Collins English Dictionary, 1994).
Quality Adjusted Life Year (QALY).	A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY

	<p>is equal to 1 year of life in perfect health.</p> <p>QALYS are calculated by estimating the years of life remaining for a patient following a particular treatment or <i>intervention</i> and weighting each year with a quality of life score (on a zero to one scale). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance. (www.nice.org.uk).</p>
Quality of Life (QoL)	A subjective assessment of one's emotional and physical well-being. (http://medical-dictionary.thefreedictionary.com).
Randomised controlled trial (RCT).	A study in which a number of similar people are randomly assigned to two (or more) groups to test a specific drug or treatment. One group (the experimental group) receives the treatment being tested, the other (the comparison or <i>control group</i>) receives an alternative treatment, a dummy treatment (<i>placebo</i>) or no treatment at all. The groups are followed up to see how effective the <i>experimental treatment</i> was. <i>Outcomes</i> are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce <i>bias</i> . (NICE, 2010).
Scottish Intercollegiate Guidelines Network (SIGN).	SIGN develops national evidence based clinical practice guidelines for NHS Scotland. (www.sign.ac.uk).
Spinal cord injury	A spinal cord injury usually begins with a sudden, traumatic blow to the spine that fractures or dislocates vertebrae. The damage begins at the moment of injury when displaced bone fragments, disc material, or <i>ligaments</i> bruise or tear into spinal cord tissue. Most injuries to the spinal cord don't completely sever it. Instead, an injury is more likely to cause fractures and compression of the vertebrae, which then crush and destroy the <i>axons</i> , extensions of nerve cells that carry signals up and down the spinal cord between the brain and the rest of the body. An injury to the spinal cord can damage a few, many, or almost all of these axons. Some injuries will allow almost complete recovery. Others will result in complete paralysis (http://www.ninds.nih.gov/disorders/sci/sci.htm).
Stroke	For your brain to function, it needs a constant blood supply, which provides vital nutrients and oxygen to the brain cells. A stroke happens when the blood supply to part of the brain is cut off and brain cells are damaged or die. (www.stroke.org.uk).
Study methodologies	Describes how research is done, including how information is collected and analysed, and why a particular method has been chosen. The overall approach taken by a research project: for example, the study could be a <i>randomised controlled trial</i> of 200 people over 1 year. (www.nice.org.uk).
Systematic review	A review in which evidence from scientific studies has been identified, appraised and synthesised in a methodical way according to predetermined criteria. It may include a <i>meta-analysis</i> . (www.nice.org.uk).
Therapeutic intervention	Intervention with the aim of treating a disease.

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